MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, October 22, 2020

Zoom Meeting

APPROVED MINUTES

I. Call to Order

Chairperson Madder called the meeting to order at 7:30 a.m.

A. Members Present and participating remotely:

Ryan Madder, MD, Chairperson – Spectrum Health – Kent County
Kyle Sheiko, Vice-Chairperson – Michigan Outpatient Vascular Institute (MOVI) – Oakland County
Khaldoon Alaswad, MD, FACC, FSCAI – Henry Ford Health System (HFHS) (Joined late)
Edouard Daher, MD – Eastlake Cardiovascular, PC – Macomb County
William R. Felten, MD, MSHAL, FACC – Midland County
Carlos Fernandez, DO – Edward Sparrow Hospital – Ingham County
Anita L. Hart, MD, FACP, SFHM – Blue Cross Blue Shield of Michigan (Joined late)
Susanne Mitchell – International Union, UAW (Joined late)
William S. Porter, RN – UAW Retiree Medical Benefits Trust – Wayne County
Mansoor A. Qureshi, MD – Trinity Health Michigan – Washtenaw County
Fadi A. Saab, MD – Advanced Cardiac & Vascular Centers for Amputation Prevention – Kent County
Frank Saltiel, MD, FACC, FSCAI – Ascension Michigan – Kalamazoo County
Steven B. H. Timmis, MD FACC – HeartPointe Cardiology (Formerly Northpointe Heart Center) – Oakland County
Justin Trivax, MD – Beaumont Health – Oakland County
Douglas J. Wunderly, MD – Bronson Healthcare Group/Advanced Cardiac Healthcare, PLC (Joined late)

B. Members Absent:

Omar E. Ali, MD – Detroit Medical Center (DMC)
Srinivas Koneru, MD – K heart & Vascular Institute, PLLC

C. Michigan Department of Health and Human Services Staff present and participating remotely:

Tulika Bhattacharya
Marcus Connolly
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Dr. Trivax, seconded by Dr. Timmis to accept the agenda as presented. Motion carried.

IV. Review of Draft Minutes – September 24, 2020

Motion by Mr. Sheiko, seconded by Dr. Qureshi to accept the minutes as presented. Motion carried.

V. Charges 6 – 8:
Charge 6 - Review current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations
Charge 7 - Review if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs
Charge 8 - Determine if a hospital that provides Primary PCI without on-site OHS should be allowed to perform left-sided cardiac ablation procedures

Shrin Hebsur, MD, Trinity Health, provided a presentation. (Attachment A)

Ilana Kutinsky, DO, Beaumont Health, provided a presentation. (Attachment B and C)

Andre Gauri, MD, Spectrum Health, provided a presentation. (Attachment D)

Discussion followed.

Motion by Mr. Sheiko, seconded by Dr. Daher to separate charges 6 and 8 from charge 7. Motion carried.

Motion by Dr. Madder, seconded by Dr. Felten to not allow left-sided ablations at this time for Charges 6 and 8. Motion carried.

Motion by Dr. Madder, seconded by Dr. Timmis, to support a subcommittee for charge 7. Motion carried.

Chairperson Madder asked SAC members to send an email to him if they are interested in participating on the subcommittee.

VI. Next Steps

Seat subcommittee for Charge 7.

Start discussions of performance of PCIs at ASCs (charges 4 and 5).

VII. Future Meeting Dates

November 19, 2020; December 17, 2020; January 14, 2021; & February 18, 2021

VIII. Public Comment

None.

Dr. Hart asked that SAC members let her know if anyone has any data requests for BMC2.

IX. Adjournment

Motion by Mr. Sheiko, seconded by Mr. Wunderly to adjourn the meeting at 9:15 a.m. Motion carried.

Left Sided Ablations at Sites Without Cardiothoracic Surgery Backup

Cardiac Cath – CON SAC Meeting

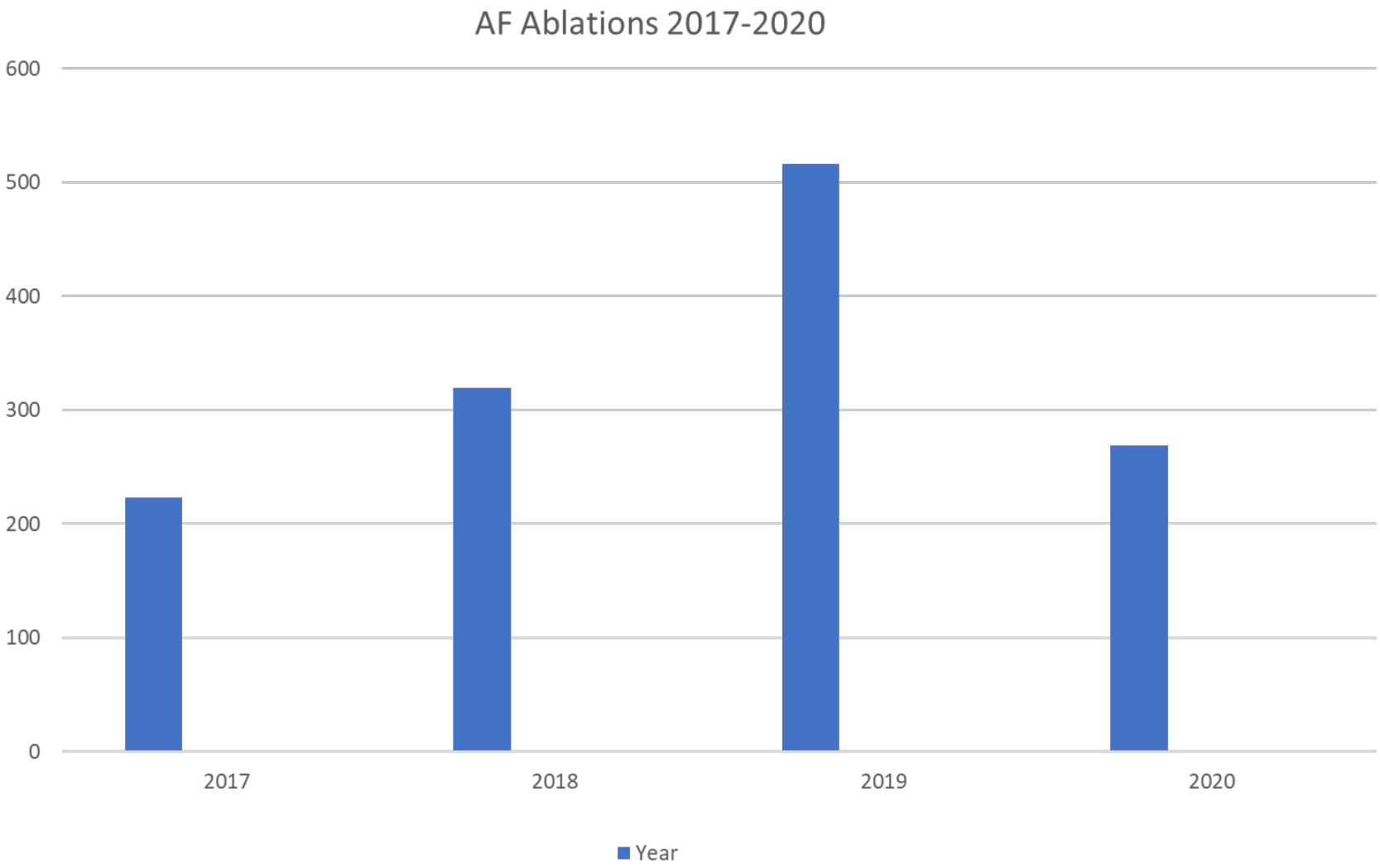
Presented By: Dr. Shrin Hebsur
Date: October 22nd, 2020

ST. JOSEPH MERCY ANN ARBOR
SAINT JOSEPH MERCY HEALTH SYSTEM

Rationale

- The field of electrophysiology is one of the fastest growing fields within cardiology and medicine/surgery
- With increased need and demand due to aging population, technology and physician comfort has improved drastically in the past 10 years.
- There is a significant limitation to perform only right sided ablations and the need for either retrograde arterial access or transeptal puncture has become paramount.
- Allowing left sided ablation in select sites where no CTS is availability is not only safe but will improve patient access and satisfaction **without** compromising safety.

Volumes


AF Ablations 2017-2020
600
500
400
300
200
100
0
2017
2018
2019
2020
Year

Complications Requiring CT Surgery

- 1 Patient in 2020 required emergent sternotomy in the EP lab.

- Patient with occluded femoral venous access. Transeptal puncture was attempted from the internal jugular vein. Pericardial effusion was loculated and unable to be drained percutaneously requiring emergent sternotomy.

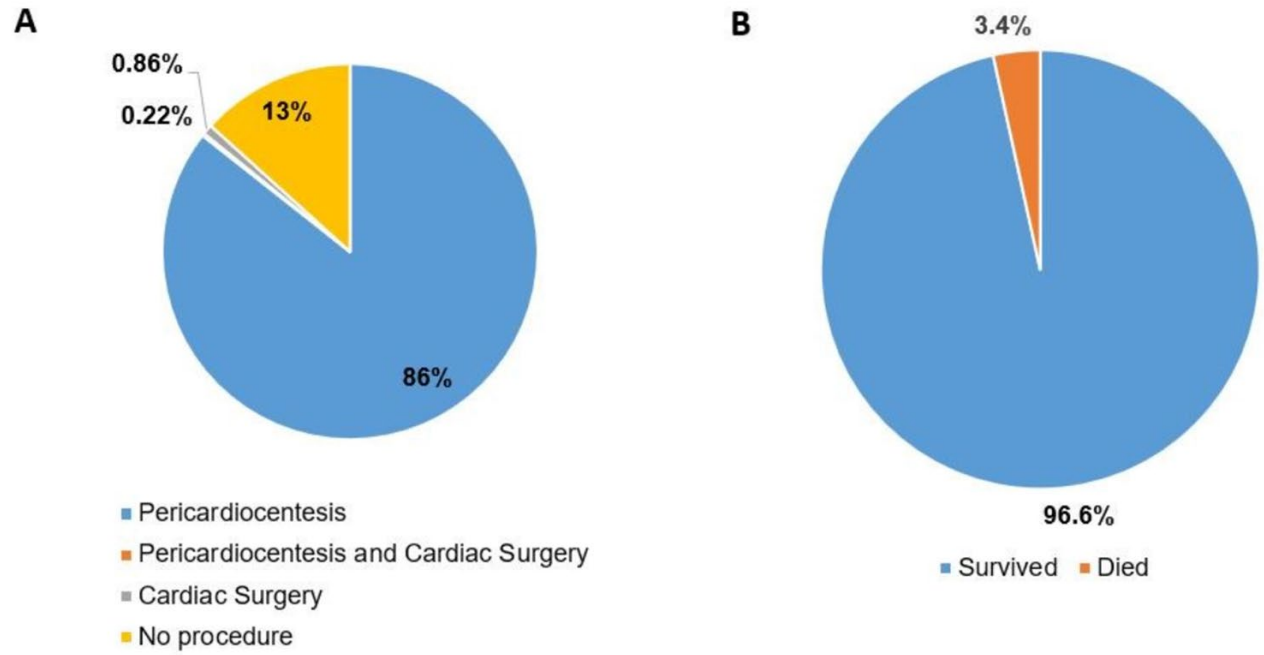
Catheter Ablation of AF With and Without On-Site Cardiothoracic Surgery

- 68,781 patients undergoing AF ablation were retrospectively analyzed.
- 2% of patients (n=1,348) had procedures at sites without CTS backup.
- Rate of cardiac perforation was 0.67% at all sites.
- OF those with perforation, 1.1% went for open heart surgery.
- All deaths occurred in sites WITH onsite cardiac surgery.
- Propensity matched analysis showed that the presence of CT surgery backup was not associated with adverse outcomes.

Daniel J Friedman, MD, FACC; Jonathan P. Piccini, Sr., MD, FACC

Catheter Ablation of AF With and Without On-Site Cardiothoracic Surgery

Figure 1



Pie charts depicting occurrence of pericardiocentesis and cardiac surgery (**A**) and survival (**B**) after cardiac perforation (n = 458) in the overall population. All deaths after perforation occurred in patients who were ablated at a hospital with CTS.

Daniel J Friedman, MD, FACC; Jonathan P. Piccini, Sr., MD, FACC

Recommendation

1. Left sided ablations SHOULD be allowed in sites without CT surgery backup provided:
    1. Operators are high volume (greater than 80 left sided cases/year) with low complication rates.
    2. Similar to PCI, a relationship with a medical facility with CTS backup is present
    3. Discretion must be used to exclude patients at high risk.

EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2016) **18**, 1352–1356
doi:10.1093/europace/euv424

CLINICAL RESEARCH
Ablation for atrial fibrillation

Who is the operator, that is the question: a multicentre study of catheter ablation of atrial fibrillation

Akinori Sairaku[1]*, Yukihiko Yoshida[2], Yukiko Nakano[1], Mayuho Maeda[2], Haruo Hirayama[2], Haruki Hashimoto[1,3], and Yasuki Kihara[1]

[1]Department of Cardiovascular Medicine, Hiroshima University Graduate School of Biomedical and Health Sciences, 1-2-3 Kasumi, Minami-ku, Hiroshima 734-8551, Japan; [2]Department of Cardiology, Cardiovascular Center, Nagoya Daini Red Cross Hospital, Nagoya, Japan; and [3]Department of Cardiology, Hiroshima City Hospital, Hiroshima, Japan

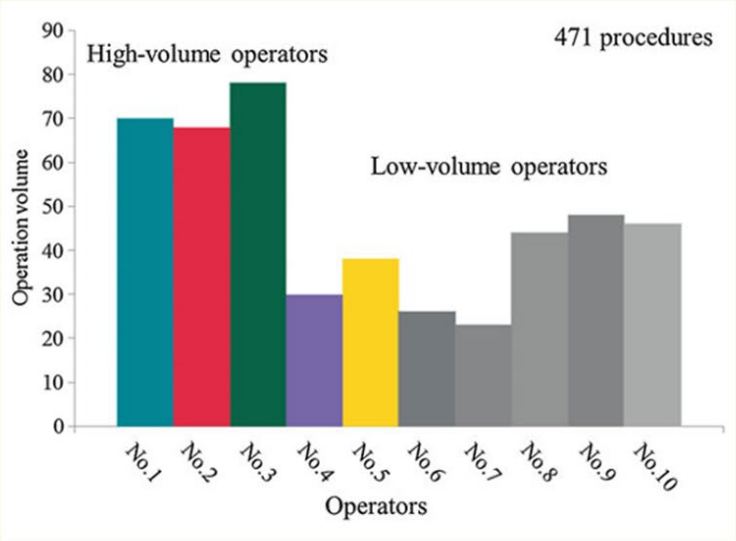


Figure 1 Operation volume of each operator during the recruitment period.

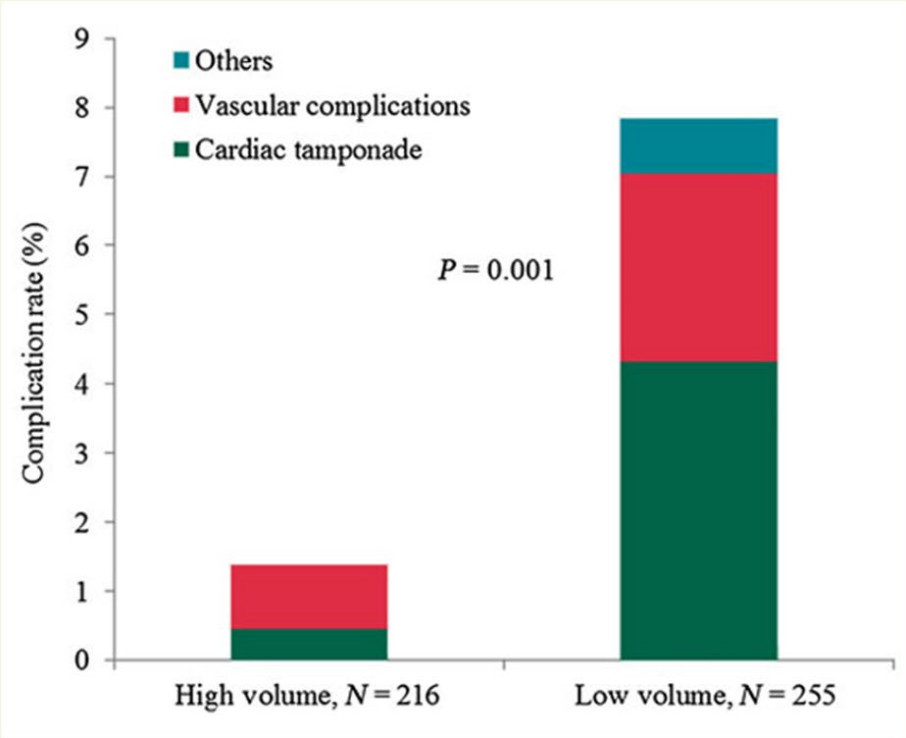


Figure 4 Complication rate. Others include one case of an intracranial haemorrhage and one case of acute renal failure requiring temporary haemodialysis.

Proposed Recommendations

- Left sided ablations such as: left atrial procedures (AF, AFL, SVT, AT) and left ventricular procedures (PVC, VT) can be done at sites without direct CT surgery access.
- Operators should be high volume, with greater than 50 left sided procedures yearly
- The hospital should have a close relationship with sites with on-site CT surgery.
- Patients should not be deemed high risk by the operating physician.

EP in an ASC

Moving low risk cases to Asc

- Improved operational efficiencies
- Economic benefits lowering overall healthcare costs
- Improves convenience for patients and payors

Low Risk EP

- Cardioversion
- TEE
- ILR implants/removal
- Device generator changes (both PPM and ICD)
- Device implants (PPM, ICD,SICD)
- Routine EP studies with right sided ablation (SVT, Flutter, RVOT PVC)

Left sided EP/ PVI can also be low risk

- <<1% complication rate < 45yrs
- 1.7% complication rate 45 -54
- 1.4 % complication rate 55-64
- 2.6% complication rate >65 yrs
- *2038 AF procedures -Marchlinski, Circulation: 2010*

HRS consensus statement 2014 – defines who should NOT be done at an ASC

- • Highly complex procedures or procedures on patients with certain conditions and comorbidities that are associated with higher procedural risk should not be performed in a freestanding laboratory (i.e., an EP laboratory that is not physically attached to a hospital).
- • Emergency cardiovascular surgical support should be immediately available in case of life-threatening bleeding complications from the extraction of chronic device leads and complex mapping/ablation procedures, particularly those requiring pericardial access.
- • High-risk procedures in critically ill patients, such as ablation of ventricular tachycardia in patients requiring extracorporeal hemodynamic support, can only be safely performed in institutions offering comprehensive programs with active engagement from electrophysiologists, surgeons, intensivists, and anesthesiologists.

- Performing EP procedures in freestanding EP laboratories on patients with clinical conditions that confer increased risk are relatively contraindicated. These include preexisting advanced heart failure and severe left ventricular dysfunction[4]; recent myocardial infarction, recent stroke, chronic kidney disease, severe chronic obstructive pulmonary disease, pulmonary hypertension, and severe/morbid obesity[5]; and severe valvular dysfunction or prosthetic heart valve, CHD (including atrial septal defect repair), active oral anticoagulation, advanced age, and pediatric age. Procedures that necessitate lesion creation close to coronary arteries, such as aortic cusp ablation[6] and epicardial ablation,[7] carry a higher risk of intraprocedural myocardial infarction and should not be performed outside a hospital.

Attachment D

SPECTRUM HEALTH

SAC Meeting: Electrophysiology Procedure Expansion

Andre Gauri MD

Current State for EP Procedures in MI

- Non complex, right sided ablations are allowed to be performed in hospitals without on-site cardiac surgery
- Complex, left sided arrhythmia (SVT,AFIB or VT) ablations are to be performed in hospitals with on-site cardiac surgery

Rationale for Current State

- Safety record for non-complex right sided ablations is favorable and need for emergent surgical rescue is very low
- Left sided ablations that require transseptal puncture or retrograde arterial approach have increased risk of major complications and potential need for emergent surgical rescue
  - Cardiac Perforation with tamponade
  - Aortic puncture during transseptal access
  - Catheter entrapment in valvular apparatus
  - Aortic Dissection
  - Coronary Artery Occlusion or Dissection
- HRS Guideline: AF ablations "should only be performed in hospitals equipped or prepared to manage these types of emergencies with access to emergency surgical support"

Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm 2017;14:e275-e444.

Topics for consideration

- Review current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations in the cases where patients have low risk Atrial Fibrillation, left-sided Premature Ventricular Contraction / Ventricular Tachycardia in the absence of severe heart failure, left sided Atrial Tachycardia, and Supraventricular Tachycardia Associated with Wolff-Parkinson-White Syndrome per the Heart Rhythm Society's (HRS) Expert Consensus Statement on Electrophysiology Laboratory Standards.

- Review if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs.

- Determine if a hospital that provides Primary PCI without on-site OHS should be allowed to perform left-sided cardiac ablation procedures.

Relevant Questions:

- Is there an access issue to meet the community needs for higher risk ablations?
- Expanding programs will result in more lower volume centers performing procedures. Is that OK for our patients?

Rationale for limiting locations for high risk ablations

Data supports that Hospitals with lower volumes of AFib Ablations have higher complications

- Perforation: 4.8 x risk
- Vascular complication: 1.5 x risk
- Any complication: 2.1 x risk
- Early Mortality: 2.5 x risk

Cheung *J Cardiovasc Electrophysiol* May 2020

Final Comments

- Unlike PCI without surgical backup where there is extensive data, there is very limited data to doing elective higher risk ablations safely in this setting
- Currently NO EP physicians are on the SAC committee

Cheung *J Cardiovasc Electrophysiol* May 2020